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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,777	07/25/2000	Gregory Kellogg	95,1408-CCC	7224
20306	7590	03/10/2005	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			LUDLOW, JAN M	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			1743	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/624,777

Applicant(s)

KELLOGG ET AL

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/25/2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. The amendment filed July 25, 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Figure 13a constitutes new matter. Note for example, that even if the squiggly lines representing non-intersecting crossovers of certain channels were found acceptable, chamber E no longer connects to chamber D, as in Figure 12, which is clearly new matter. The examiner notes that the instant application is a Divisional, and relies upon a copy of the declaration field in the parent application. Such an application should be a TRUE copy of the parent application, which this application is not.

2. Applicant is required to cancel the new matter in the reply to this Office Action.

3. This application repeats a substantial portion of prior Application No. 08/910726, filed August 17, 1997, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: There is no description of Figure 13A and the reference characters used therein. Note that applicant has been inconsistent in the use of reference characters between Figures 12 and 13, and the combination of the two figures as presented in

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Figure 13A introduces primed reference characters without description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the combination of an entry port and first channel as claimed in claim 1 communicating with the first chamber A as shown in Figure 3 must be shown or the feature(s) cancelled from the claims. Therefore, the combination of parts a-e and f-i of claim 3 must be shown or the feature(s) canceled from the claim(s). Therefore, each of the microchannels and the fluid chambers having air displacement channels for venting to the surface of claims 3 and 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

- a. Note that Figure 13, showing the embodiment of Claim 1, lacks an entry port and first channel.

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6. Note that the disclosure teaches that the sample chamber A of figure 13 could be supplied by a metering system like that of figure 12, but it is unclear how the two systems would be superimposed in that placement of the overflow chamber (D in figure 12) distal of the sample chamber (E in figure 12, A in figure 13) would require crossing the overflow capillary (C in figure 12) with one of capillaries F or G of figure 13.

7. Note that Figure 13, showing the embodiment of claim 1, shows ONE air displacement channel (H), not one for each channel and chamber.

8. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. There is no description of where and how an inlet port and first channel would be connected to chamber A in Figure 13. There is no description of where or how **each** channel and chamber would have an air displacement channel, as found at the end of claims 1 and 3. The combination claimed in claims 3-4 is not described in such a way as to enable one skilled in the art to practice the invention. Elements a-e are described in Example 2 and figure 12. Elements f-l are described in example 3 and figure 13 and a suggestion to combine the two is made at page 46, lines 14-17, were it is alleged that such combination is within ordinary skill, but no direction as to how to achieve the combination is given. The examiner notes that superimposing figure 12 on figure 13 by matching chamber E of figure 12 to chamber A of figure 13 is not possible because the overflow capillary C of figure 12 crosses capillary F of figure 13.

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10. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. There is no description of where and how an inlet port and first channel would be connected to chamber A in Figure 13. There is no description of where or how **each** channel and chamber would have an air displacement channel, as found at the end of claims 1 and 3. The combination claimed in claims 3-4 is not described in such a way as to enable one skilled in the art to practice the invention. Elements a-e are described in Example 2 and figure 12. Elements f-l are described in example 3 and figure 13 and a suggestion to combine the two is made at page 46, lines 14-17, where it is alleged that such combination is within ordinary skill, but no direction as to how to achieve the combination is given. The examiner notes that superimposing figure 12 on figure 13 by matching chamber E of figure 12 to chamber A of figure 13 is not possible because the overflow capillary C of figure 12 crosses capillary F of figure 13.

12. Claims 1-4 are objected to because of the following informalities: In claim 1, part h), line 6, and claim 3, part i), line 6, before "fluid chamber", "second" should be "first". Appropriate correction is required.

13. Applicant is requested to carefully review the disclosure and claims for any additional errors of this nature. The above changes make the claims correspond to the embodiment of Figure 13. The suggestion corrects the claim in that the channel

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connecting the third (C) and second (B) chambers as described corresponds to channel H which is an air displacement channel, not channel G which is the fluid transfer channel corresponding in function to the third channel as claimed (connecting the first and third chambers for displacement of the sample from A to C).

14. Applicant's arguments filed December 21, 2004 have been fully considered but they are not persuasive.

15. Applicant argues that Figure 13A shows the features of claims 1 and 3, but Figure 13A constitutes new matter. With respect to the air displacement channels and vents, the examiner notes that claim 1 corresponds to the second embodiment and claim 3 corresponds to the third embodiment. Note that while in the first and third embodiments, the specification states that in some embodiments, the platform also comprises air displacement channels venting to the surface (see, e.g., col. 5, lines 15-17 and col. 10, lines 22-24 of 6,143,248 issuing from the parent), only with respect to the fourth embodiment is it disclosed that each of the microchannels and chambers include displacement channels and vents (col. 11, lines 50-54 of 6,143,248). The specification is silent as to the second embodiment containing air displacement channels. The examiner notes that the file wrapper for application 08/910726 is unavailable, and therefore the examiner cannot determine if the claims as originally filed support the present claim language.

16. Applicant argues that the disclosure teaches that plural layers can be used to form various channels, but Figures 11A-E have not been described in detail, and it is unclear whether Figure 11B shows channels or electrical connections. Further, Figure

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13A constitutes new matter and does not accurately combine Figures 12 and 13, even if the somewhat nebulous teaching concerning various layers were held to be adequate and enabling written description.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Kopf-Sill ('702) teaches a rotor and method of use. An entry port 26 is in fluid communication with a capillary 34, 36, 42 (instant first channel) which is connected to a first fluid chamber 50. A second displacement fluid chamber 64 is coupled to the first chamber 50 via second channel 84. Fluid displaced from chamber 50 is moved to third fluid chamber 98, 100 via third channel 88. See, e.g., figure 1 and figures 10-15. A sample of 50-200 ul is used and capillary depths of .3 and .6 mm are employed in the specific example (col. 7, lines 10, 61-62). Vents are provided throughout the device ("x" in figure 2). However, the inlet and outlet of the third channel are opposite the positions claimed. That is, flow is from an inlet outward toward the outlet, whereas in the instant claims and as shown in Figure 13, in the instant third channel, flow is inward from the inlet of the third channel (junction of channel G and chamber A) to the outlet (junction of channel G and chamber C).

19. Schembri ('193) teaches a rotor and method of use. An entry port 5 is in fluid communication with an overflow capillary 13 and a metering capillary 7. The overflow capillary is in communication with an overflow chamber 11 and the metering capillary 7 is connected to a first fluid chamber 15. A displacement fluid chamber 39 is coupled to the first chamber 15 via channels 41. Fluid displaced from chamber 15 is moved to



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third fluid chamber 31 via channel 33. See, e.g., figures 1-3 and col. 7, especially, lines 24, 51, and col. 8. Capillary dimensions of .05-.25 mm are employed in the specific example (col. 7, lines 45-46). With respect to curved proximal channel ends, the capillaries have gradual sloped sides as seen in the figures. With respect to air displacement channels, it is the examiners position that port 19 and or passage 33 permit air flow (col. 8, lines 20-25). However, the inlet and outlet of the third channel are opposite the positions claimed. That is, flow is from an inlet outward toward the outlet, whereas in the instant claims and as shown in Figure 13, in the instant third channel, flow is inward from the inlet of the third channel (junction of channel G and chamber A) to the outlet (junction of channel G and chamber C).

20. Braynin et al. ('606) teach a rotor and method of use. An entry port 22 is in fluid communication with an overflow capillary 46 and a metering capillary 40. The overflow capillary is in communication with an overflow chamber 44 and the metering capillary 40 is connected to a first fluid chamber 60. A displacement fluid chamber 80 is coupled to the first chamber 60 via channel 82. Fluid displaced from chamber 60 is moved to third fluid chamber 92 via channel 94. Samples of .005-.03 ml are used (col. 4, line 15).

Capillary dimensions of .1- 1 mm are employed in the specific example (col. 6, lines 50-55). With respect to curved proximal channel ends, the capillaries have gradual sloped sides as seen in the figures. With respect to air displacement channels, vent ports (e.g., 24, 26, 28, 30) are provided. However, the inlet and outlet of the third channel are opposite the positions claimed. That is, flow is from an inlet outward toward the outlet, whereas in the instant claims and as shown in Figure 13, in the instant third channel,

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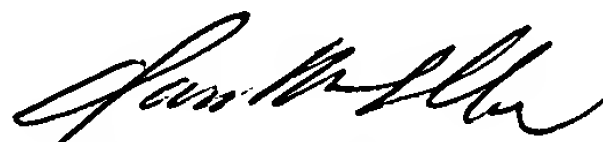
flow is inward from the inlet of the third channel (junction of channel G and chamber A) to the outlet (junction of channel G and chamber C).

21. Schembri ('643) teaches a channel 134 having an inlet outward of the outlet as in the instant claim, but fails to teach or suggest the fluid displacement feature of the instant claims. There is no motivation to combine Schembri ('643) with the preceding references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

Jml  
March 6, 2005